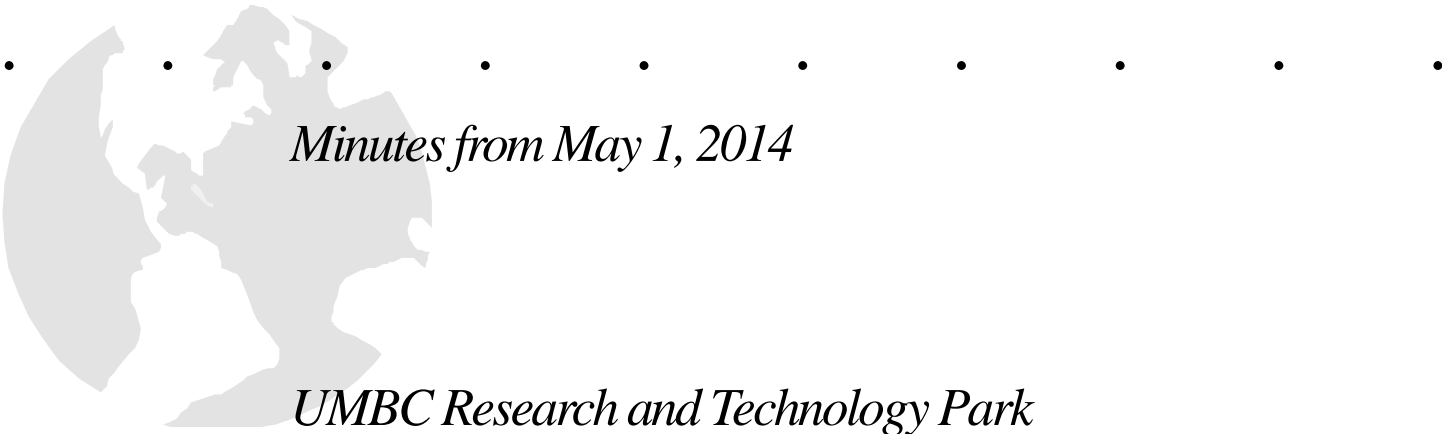




Maryland Pharmacy Program PDL P&T Meeting



Minutes from May 1, 2014

UMBC Research and Technology Park



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Minutes- May 1, 2014

Attendees:

P&T Committee

Jenel Steele Wyatt (Chairperson); Zakiya Chambers (Vice Chairperson); Esther Alabi; Sharon Baucom; John Boronow; Helen Lann; Evelyn White Lloyd; Marie Mackowick; Ryan Scott Miller; Brian Pinto; Karen Vleck

DHMH Staff

Athos Alexandrou (Maryland Pharmacy Program Director); Dixit Shah (Maryland Pharmacy Program Deputy Director); Renee Hilliard (Division Chief, Clinical Pharmacy Services), Mona Gahunia (Chief Medical Officer); Lisa Burgess (Maryland Pharmacy Program Child Psychiatrist); Paul Holly (Consultant Pharmacist to Maryland Pharmacy Program); Dennis Klein (Maryland Pharmacy Program Pharmacist)

Health Information Designs (HID)

Joe Paradis, PharmD; Naana Osei-Boateng, PharmD

Provider Synergies/Magellan Medicaid Administration (PS/MMA)

Matthew Lennertz, PharmD

Proceedings:

The public meeting of the PDL P&T Committee was called to order by the Chairperson, Dr. Steele Wyatt, at 9:00 a.m. The meeting began with brief introductions of all the representatives including the P&T Committee members, DHMH, HID, and PS/MMA. The Committee then approved the minutes from the previous P&T Committee meeting held on November 7, 2013.

Dr. Steele Wyatt then asked Mr. Alexandrou to provide a status update on the Maryland Medicaid Pharmacy Program (MMPP). Mr. Alexandrou explained that the PDL is in its eleventh year and has saved tens of millions of dollars on prescription drugs thus allowing the State to manage costs without reducing covered services. The Committee was reminded that the Program's goal is to provide the safest, clinically sound and most cost effective medications to Maryland Medicaid members.

Mr. Alexandrou reemphasized the Peer Review Program implemented in late 2011 for children and adolescents taking antipsychotic medications. The goal of the program is to

achieve patient safety by improving patient monitoring for adverse effects and ensuring the patient's medication regimen is appropriate. The Program has been rolled out in three phases: phase I was implemented in October of 2011 and included children under the age of 5, phase II was implemented in July of 2012 and included children under the age of 10, and phase III was implemented in January of 2014 and included children under the age of 18.

Mr. Alexandrou stated that as part of the State FY 2012 budget, the Maryland General Assembly asked the Department to convene a workgroup and provide recommendations "to develop a system of integrated care for individuals with concurrent serious mental illness and substance abuse issues." In response, the Department undertook the initiative to develop a model for an integrated behavioral health service delivery and financing system. The development of the model included significant input from a diverse group of stakeholders, representing individuals with behavioral health needs, providers and advocates.

The new behavioral health model focuses on implementing a performance-based carve-out of mental health and substance use services and on merging the Mental Hygiene Administration and the Alcohol and Drug Abuse Administration into the Behavioral Health Administration. The carved out services will be managed through an Administrative Services Organization (ASO) on a fee-for-service basis. The Department released a Request For Proposals for an ASO earlier this year and plans to implement the new system in January 2015. This behavioral health carved-out model will also include some classes of drugs that are currently covered under the Managed Care Organization's (MCO) pharmacy benefit.

Mr. Alexandrou explained that in November 2013, the Centers for Medicare and Medicaid Services (CMS) began publishing a national price benchmark for pharmacy reimbursement based on an average acquisition drug cost. The benchmark, known as the National Average Drug Acquisition Cost (NADAC), provides state Medicaid agencies with a more accurate and responsive pricing methodology for outpatient covered drugs. Hence, the Maryland Medicaid Pharmacy Program contracted with Myers and Stauffer LC to study the feasibility of replacing our current pricing methodology with the NADAC. DHMH is currently reviewing the results of the feasibility study to determine what changes, if any, will be made.

Mr. Alexandrou emphasized that the landscape for treatment of hepatitis c has evolved since the appearance of direct acting agents in 2011. The arrival of Sovaldi and Olysio has further expanded the treatment options and additional products are expected in the future. DHMH has developed clinical criteria which can be utilized by the MCO's and Fee for Service program to assure safe and appropriate use of these medications.

Mr. Alexandrou reiterated the mechanism to obtain a PDL prior authorization (PA) is less cumbersome than many other PA processes. Maryland Medicaid's PDL provides more options than many other states and the private sector. Furthermore, mental health drugs are grandfathered. The PDL is also accessible through Epocrates. More importantly, prescribers are cooperating with the PDL and current compliance is over 94%.

The pharmacy hotline remains active averaging about 1500 calls each month with about 9% of them relating to the PDL. Mr. Alexandrou thanked the Committee for their dedication and commitment to serving the citizens of the State of Maryland.

Dr. Steele Wyatt acknowledged that it was time for the public presentation period to begin. As customary, there is no question/answer period; and pre-selected speakers have 5 minutes with a timer.

Name	Affiliation	Class/Drug of Interest
Ruchir Parikh	Boehringer Ingelheim	Pradaxa
Alan Rosen	Forest Pharmaceuticals	Linzess
Mohan Bikkina	Purdue Pharma	Butrans and Oxycontin
Jasmin Graziano	Biogen Idec	Tecfidera
Phil Mendys	Pfizer	Eliquis
Erin Paul	Actelion	Opsumit, Tracleer and Ventavis
Alison Martens	Meda Pharmaceuticals	Aerospan
Melanie Jardim	United Therapeutics	Adcirca and Tyvaso
Domenic Mantella and Andrea Windsheimer	Novo Nordisk	Norditropin and Victoza
Jodi Walker	Abbvie	Creon and Androgel
Mark Angeles	AstraZeneca	Farxiga and Bydureon
Deanna Phillips	Amgen	Neupogen and Neulasta
Phillip Wiegand	Janssen	Olysio, Invokana, and Xarelto

Mr. Shah presented the Xerox prior authorization report in place of Karriem Farrakhan, PharmD from Xerox, the claims processor. Mr. Shah indicated that there was a reduction in prior authorizations from the previous quarter because Cymbalta was changed to a preferred drug. Dr. Pinto then questioned why discrepancies existed between the number of prescription claims processed and the number of prior authorizations that occurred for a drug. Dr. Pinto suggested that it may be due to certain drugs being grandfathered so they would not need a prior authorization. Mr. Shah indicated that grandfathering occurred for antipsychotics. Dr. Steele Wyatt suggested that the question should be forwarded to Dr. Farrakhan and Mr. Shah agreed.

Dr. Steele Wyatt stated that there were 32 classes that had no recommended changes from the existing PDL. Dr. Steele Wyatt also stated that Dr. Pinto would recuse himself should any conversation arise in the angiotensin modulator combinations, angiotensin

modulators, and lipotropics, other classes due to a potential conflict of interest. Dr. Pinto advocated for the addition of at least one of the newer oral agents, Eliquis, Pradaxa or Xarelto to the anticoagulants' class. Dr. Steele Wyatt asked if Dr. Pinto had a suggestion to add a particular agent and he indicated that he was asking to consider any of the three. Additional discussion ensued. Dr. Baucom indicated that since the prior authorization process was relatively easy, she was in favor of keeping all three drugs non-preferred.

Dr. Boronow asked Dr. Lennertz to provide additional information about the abuse deterrent aspects of certain long acting opioid formulations. Dr. Lennertz explained that abuse deterrent formulations are formulated to reduce crushing and snorting or injecting the drug, but not for oral abuse. Dr. Lennertz also suggested that in the future abuse deterrence may be worth consideration, but there was no specific information at present to change his recommendations.

Dr. Baucom asked if warfarin related hospitalizations were tracked. Dr. Steele Wyatt responded that she was not aware of a tracking system and that it is likely beyond the scope of the committee. Dr. Wyatt then said that since no motions were made in regards to specific recommendations, the recommendations in the 32 classes were approved.

Class	Voting Result
Analgesics, Narcotics (Long Acting)	Maintain current Preferred agents: generics (fentanyl patch, methadone, morphine sulfate SR), Kadian
Androgenic Agents	Maintain current Preferred agents: Androgel, Testim
Angiotensin Modulator Combinations	Maintain current Preferred agents: generics (amlodipine/benazepril), Azor, Exforge, Exforge HCT, Tribenzor
Angiotensin Modulators	Maintain current Preferred agents: generics (benazepril, benazepril/HCTZ, captopril, captopril/HCTZ, fosinopril, fosinopril/HCTZ, irbesartan, irbesartan/HCTZ, lisinopril, lisinopril/HCTZ, losartan, losartan/HCTZ, quinapril, quinapril/HCTZ, ramipril, telmisartan, telmisartan/HCTZ, valsartan/HCTZ), Diovan

Class	Voting Result
Antibiotics, GI	Maintain current preferred agents: generics (metronidazole tablets, neomycin), Alinia, Vancocin
Antibiotics, Topical	Maintain current preferred agent: generics (bacitracin OTC, bacitracin/polymyxin OTC, gentamicin, mupirocin ointment, triple antibiotic OTC)
Antibiotics, Vaginal	Maintain current preferred agents: generics (clindamycin, metronidazole vaginal), Cleocin ovule
Anticoagulants	Maintain current preferred agents: generics (enoxaparin, warfarin), Fragmin
Antifungals, Topical	Maintain current Preferred agents: generics (clotrimazole (Rx and OTC), clotrimazole/betamethasone, econazole, ketoconazole cream, ketoconazole shampoo, miconazole OTC, nystatin, nystatin/triamcinolone, terbinafine OTC, tolnaftate OTC, tolnaftate aero powder)
Antivirals, Oral	Maintain current Preferred agents: generics (acyclovir, amantadine, rimantadine, valacyclovir)
Antivirals, Topical	Maintain current Preferred agents: generics (acyclovir ointment), Abreva OTC, Denavir
Benign Prostatic Hyperplasia	Maintain current Preferred agents: generics (alfuzosin, doxazosin, finasteride, tamsulosin, terazosin)
Beta Blockers	Maintain current Preferred agents: generics (atenolol, atenolol/chlorthalidone, bisoprolol/hctz, carvedilol, labetalol, metoprolol tartrate, nadolol, pindolol, propranolol, propranolol/HCTZ, sotalol, sotalol AF), Toprol XL
Bladder Relaxant Preparations	Maintain current Preferred agents: generics (oxybutynin, oxybutynin ER), Toviaz
Bone Resorption Suppression and Related Agents	Maintain current Preferred agents: generics (alendronate, calcitonin salmon nasal), Fortical

Class	Voting Result
Calcium Channel Blockers	Maintain current Preferred agents: generics (amlodipine, diltiazem, nifedipine, nifedipine ER, verapamil, verapamil ER), Cardizem LA
Colony Stimulating Factors	Maintain current Preferred agents: Neupogen
Erythropoietins	Maintain current Preferred agents: Aranesp, Procrit
Growth Hormones	Maintain current Preferred agents: Genotropin, Norditropin, Nutropin, Nutropin AQ
Hypoglycemics, Incretin Mimetics and Enhancers	Maintain current Preferred agents: Byetta, Januvia, Janumet, Janumet XR, Jentadueto, Juvisync, Tradjenta, Symmlin
Hypoglycemics, Insulins	Maintain current Preferred agents: Humalog, Humulin, Lantus, Novolin, Novolog
Hypoglycemics, Meglitinides	Maintain current Preferred agents: generics (nateglinide, repaglinide)
Hypoglycemics, TZDs	Maintain current Preferred agents: generics (pioglitazone, pioglitazone/glimepiride)
Immunosuppressives, Oral	Maintain current Preferred agents: generics (azathioprine, cyclosporine, cyclosporine modified, mycophenolate mofetil, sirolimus, tacrolimus)
Lipotropics, Other	Maintain current Preferred agents: generics (cholestyramine, fenofibric acid, gemfibrozil, niacin ER) Niacor, Tricor,
Lipotropics, Statins	Maintain current Preferred agents: generics (atorvastatin, fluvastatin, lovastatin, pravastatin, simvastatin), Lescol XL, Simcor
Macrolides/Ketolides	Maintain current Preferred agents: generics (azithromycin, erythromycin base), E.E.S., Ery-Tab, EryPed, Erythrocin
Multiple Sclerosis	Maintain current Preferred agents: Avonex, Betaseron, Copaxone 20mg, Rebif
Pancreatic Enzymes	Maintain current Preferred agents: generics (pancrelipase), Creon, Zenpep

Class	Voting Result
Phosphate Binders	Maintain current Preferred agents: generics (calcium acetate), Calphron OTC
Platelet Aggregation Inhibitors	Maintain current Preferred agents: generics (clopidogrel, dipyridamole, ticlopidine), Aggrenox
Skeletal Muscle Relaxants	Maintain current Preferred agents: generics (baclofen, carisoprodol 350mg, chlorzoxazone, cyclobenzaprine, dantrolene, methocarbamol, orphenadrine, tizanidine tablets)

Immediately following were reviews of 17 classes with modified recommendations from the existing PDL and reviews of 7 classes with single drug reviews. Dr. Steele Wyatt indicated that Dr. Baucom would recuse herself should any conversation arise in the hepatitis c or inhaled antibiotics classes due to a potential conflict of interest. The following table reflects the voting results for each of the affected therapeutic categories:

Class	Voting Result
Acne Agents, Topical	<p>ADD: benzoyl peroxide OTC</p> <p>REMOVE: benzoyl peroxide cleanser, benzoyl peroxide gel, tretinoin micro, Differin gel</p> <p>Other Preferred Agents: generics (benzoyl peroxide RX, clindamycin, erythromycin, tretinoin), Azelex, Differin cream, Differin lotion, Panoxyl OTC</p>
Analgesics, Narcotics (Short Acting)	<p>REMOVE: dihydrocodeine/asa/caffeine, oxycodone/asa, pentazocine/naloxone</p> <p>Other Preferred Agents: generics (apap/codeine, butalbital/apap/codeine/caffeine, butalbital/asa/codeine/caffeine, codeine tablets, hydrocodone/apap, hydrocodone/ibuprofen, hydromorphone tablets, morphine sulfate tablets, oxycodone, oxycodone/apap, pentazocine/apap, tramadol, tramadol/apap)</p>

Class	Voting Result
Antibiotics, Inhaled	<p>ADD: Tobi Podhaler (Step Therapy)</p> <p>Other Preferred agents: Tobi inhalation solution</p>
Antiemetic/Antivertigo Agents	<p>REMOVE: Marinol</p> <p>Other Preferred Agents: generics (dimenhydrinate, dimenhydrinate OTC, meclizine, meclizine OTC, metoclopramide, ondansetron, prochlorperazine, promethazine) Emend capsules, TransDerm Scop</p>
Antifungals, Oral	<p>ADD: griseofulvin suspension</p> <p>REMOVE: griseofulvin ultra, nystatin powder</p> <p>Other Preferred agents: generics (fluconazole, ketoconazole, nystatin suspension and tablets, terbinafine)</p>
Anti-Migraine Agents	<p>ADD: rizatriptan, rizatriptan ODT</p> <p>Other Preferred agents: generics (sumatriptan), Relpax</p>
Antiparasitics, Topical	<p>ADD: Ulesfia</p> <p>REMOVE: Eurax cream</p> <p>Other Preferred Agents: generics (permethrin OTC, permethrin Rx, piperonyl/pyrethrins OTC, piperonyl/pyrethrins/permethrin OTC)</p>
Cephalosporin and Related Agents	<p>REMOVE: cefadroxil suspension and tablets, Suprax tablets</p> <p>Other Preferred agents: generics (amoxicillin/clavulanate, cefaclor, cefaclor ER, cefadroxil capsules, cefdinir, cefprozil, cefuroxime, cephalexin) Suprax capsules and suspension</p>
Fluoroquinolones	<p>REMOVE: levofloxacin solution</p> <p>Other Preferred agents: generics (ciprofloxacin, levofloxacin tablets)</p>

Class	Voting Result
Hepatitis C Agents	REMOVE: ribavirin dose pack ADD: Sovaldi Other Preferred Agents: generics (ribavirin) Pegasys, Peg-Intron, Incivek, Victrelis
Hypoglycemics, SGLT2	ADD: Invokana (Step Therapy)
Irritable Bowel Syndrome	ADD: Amitiza, Linzess
Opiate Dependence Treatments	ADD: generics (buprenorphine, naltrexone), Suboxone film
Proton Pump Inhibitors	REMOVE: lansoprazole OTC, omeprazole OTC Other Preferred Agents: generics (lansoprazole, omeprazole, pantoprazole) Prevacid Solutab, Protonix suspension
Pulmonary Arterial Hypertension Agents	REMOVE: Adcirca Maintain current Preferred agents: generics (sildenafil), Letairis, Tracleer, Ventavis
Tetracyclines	REMOVE: doxycycline monohydrate 75mg and 150mg, minocycline tablets Other Preferred Agents: generics (doxycycline hyclate, doxycycline monohydrate 50mg and 100mg, minocycline capsules, tetracycline)
Ulcerative Colitis	ADD: Apriso Other Preferred Agents: generics (balsalazide, sulfasalazine, sulfasalazine DR) Asacol, Canasa, Delzicol
Single Drug Reviews	Voting Result
Anticonvulsants	DO NOT ADD: Aptiom, Fycompa
Antidepressants, Other	DO NOT ADD: Brintellix, Fetzima, Khedezla
Antipsychotics	DO NOT ADD: Adasuve, Versacloz
COPD Agents	DO NOT ADD: Anoro Ellipta

Single Drug Reviews	Voting Result
Cytokine and CAM Antagonists	DO NOT ADD: Actemra Syringe
Glucocorticoids, Inhaled	DO NOT ADD: Aerospan, Breo Ellipta
NSAIDs	DO NOT ADD: Pennsaid Pump, Zorvolex

~ The State will continue to monitor the pricing of generic drug products (both new and existing) and continues to maintain autonomy to modify or adjust the PDL status of multi-source brands and/or generic drugs that may become necessary as a result of fluctuations in market conditions (e.g. changes in Federal rebates, supplemental rebates, etc.).

During the review of the oral antifungals class, Dr. Miller asked if there would be a griseofulvin product on the PDL with the removal of griseofulvin micro. Dr. Lennertz said that there would not be a preferred griseofulvin product given the recommendations. Dr. Miller indicated that he felt a griseofulvin product should be on the PDL due to some indications and motioned for the addition of griseofulvin suspension. Dr. Hilliard cautioned the group to consider the two percent utilization of griseofulvin, and to keep in mind the easy prior authorization process. Dr. Miller indicated that the drug is probably not used often, but thought it made sense to avoid the extra step in the few requests. The motion to add the recommendation of griseofulvin suspension to the PDL carried.

During the review of the fluoroquinolones class, Dr. Pinto asked if other members were concerned about the utilization of ciprofloxacin due to resistance patterns in the community. Dr. Hilliard reminded the members that ciprofloxacin was the preferred fluoroquinolone for urinary tract infections and that is likely the driver of usage. Further discussion ensued. Since the discussion did not involve a change in recommendation, the recommendations were approved.

During the review of the hepatitis C class, Dr. Alabi asked the difference between ribavirin and ribavirin dose pack. Dr. Lennertz stated that the dose pack is convenience packaging and the state has regulations surrounding convenience packaging. Dr. Pinto asked given the high cost of hepatitis medications if a system was being implemented to track the patients and their adherence. Dr. Hilliard stated that clinical criteria are currently in development which includes laboratory monitoring for adherence. Dr. Pinto asked if a health coach or similar person would be used to ensure the patient is adherent to the therapy. Dr. Hilliard stated that the specialist that prescribes the medication will also need to submit a treatment plan and the specialty prescriber is responsible for coaching and monitoring therapy. Dr. Gahunia indicated that an adherence assessment is required but a health coach would be hard to implement because most of the patients are in MCOs. Since the discussion did not involve a change in recommendation, the recommendations were approved.

During the review of the opiate dependence agents class, Dr. Baucom stated that Suboxone was probably the most abused drug in the state correctional facilities and wasn't introduced to their formulary for the abuse potential. Further discussion ensued. Since the discussion did not involve a change in recommendation, the recommendations were approved.

The next meeting is scheduled for November 6th, 2014. With no further business, the public meeting adjourned at 11:21 a.m.